



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,151	12/02/2003	David K. Swanson	03-0515 (US01)	5305
41696 7590 05/21/2007 VISTA IP LAW GROUP LLP 12930 Saratoga Avenue Suite D-2 Saratoga, CA 95070			EXAMINER ROANE, AARON F	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 05/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

H

Office Action Summary	Application No. 10/727,151	Applicant(s) SWANSON, DAVID K.	
	Examiner Aaron Roane	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 28-43 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,28-30,38 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-37,40 and 41 is/are allowed.
- 6) ☒ Claim(s) 1-8,11-20,31,42 and 43 is/are rejected.
- 7) ☐ Claim(s) 32 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11-20, 31-37, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Gadsby et al. (USPN 5,309,909).

Regarding claim 1, Gadsby et al. disclose a carrier (12) movable between an unstressed state (figure 3) and a deflected and stressed state (figure 4); a tissue stimulation element (18, individually or collectively) supported by the carrier; and a tissue engagement device (22) carried by the carrier, configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state, see col. 3, line 53 through col. 6, line 29 and figures 1-4.

Regarding claim 2, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Regarding claims 3-5, Gadsby et al. further disclose the carrier includes a curved interior and first and second end portions, in the form of first and second tissue stimulation elements (the first end portion in the form of a tissue stimulation element is 18 located closest to 36 and the second end portion in the form of a tissue stimulation element is 18 located farthest from 36) and an interior portion and the carrier is configured such that the interior portion will be in spaced relation to the tissue when the end portions are in contact with the tissue and the carrier is in the unstressed state, see figures 1-4.

Regarding claims 6 and 7, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Regarding claims 11 and 12, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Regarding claims 19 and 20, Gadsby et al. further disclose a flexible carrier (16) that is non-linear when in a relaxed state, see figures 3 and 4.

Regarding claim 31, Gadsby et al. disclose the claimed invention, see col. 3, line 53 through col. 6, line 29 and figures 1-4. Gadsby et al. disclose that the body (14) is 1mm in thickness, see col. 4, lines 7-11 and figures 3 and 4. It is therefore straightforward to deduce that there is a point along the length of (18) that has a diameter between 0.5mm and 1mm, since (18) is cone shaped and at the point it has zero diameter while at its base.

Art Unit: 3739

(interface of 12 and 18) it has a diameter of a little greater than 1mm as may be seen from figures 3 and 4.

Regarding claim 42, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Claim 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tetzlaff et al. (USPN 6,277,117).

Regarding claims 13-15, Tetzlaff et al. disclose a forceps apparatus comprising a tissue stimulation element (electrodes 110 and 120) supported by the carrier, a means for securing (20) the forceps apparatus to the tissue structure by engaging a single side of the tissue structure (outside of a vessel) and pressing the stimulation element against the single side of the tissue structure, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tetzlaff et al. (USPN 6,277,117) in view of Nezhat (USPN 6,162,622).

Regarding claims 1 and 42, Tetzlaff et al. disclose a forceps apparatus comprising a means for securing or carrier (20) movable between an unstressed state (open and non-engaged state) and a deflected and stressed state (closed and/or tissue clamping engaged state); a tissue stimulation element (electrodes 110 and 120) supported by the carrier, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular. Tetzlaff fails to disclose a tissue engagement device carried by the carrier, the tissue engagement device being configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state and wherein the tissue engagement device comprises a sharpened end for piercing tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the electrodes (tissue stimulation elements) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Regarding claim 8, Tetzlaff et al. disclose a forceps apparatus comprising a means for securing or carrier (20) movable between an unstressed state (open and non-engaged state) and a deflected and stressed state (closed and/or tissue clamping engaged state); a tissue stimulation element (electrodes 110 and 120) supported by the carrier, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular. Tetzlaff fails to disclose first and second tissue piercing members carried by the carrier and to secure the carrier to the tissue in the deflected and stressed state.

Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the electrodes (tissue stimulation elements) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Regarding claim 16, Tetzlaff et al. disclose a forceps apparatus comprising a tissue stimulation element (electrodes 110 and 120), an anchor (20), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by pressing the stimulation element against the tissue, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular. Tetzlaff et

al. fail to disclose that the anchor secures the surgical apparatus to the tissue by piercing the tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. The combination provides a forceps device that secures to tissue via pressing and tissue piercing teeth. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the electrodes (tissue stimulation elements) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Regarding claims 17 and 18, Tetzlaff et al. disclose the claimed invention.

Regarding claim 19, Tetzlaff et al. further disclose anchor includes a flexible carrier (proximal portion of 20 comprising 12, 14, 32 and 34), see col. 4, lines 35-67 and figures 1-8.

Regarding claim 20, Tetzlaff et al. disclose the claimed invention, see figure 3 where 12 and 14 are not aligned.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tetzlaff et al. (USPN 6,277,117) as applied to claim 13 above, and further in view of Nezhat (USPN 6,162,622).

Regarding claim 43, Tetzlaff et al. disclose the disclosed invention except for reciting the means for securing the surgical apparatus to the tissue comprises a sharpened end for piercing tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the forceps (means for securing) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tetzlaff et al. (USPN 6,277,117) as applied to claim 13 above, and further in view of Nezhat (USPN 6,162,622).

Regarding claim 43, Tetzlaff et al. disclose the claimed invention except for the element associated with the means for securing having sharpened end for piercing tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288)

Art Unit: 3739

that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the forceps (means for securing) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Response to Arguments

Applicant's arguments filed 4/27/2007 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

On page 8, last paragraph, Applicant asserts "Gadsby refers to the electrode 12 as the entire device. (Gadsby, col. 3, lines 53-60; Fig. 1). The entire device 12, however, is not moveable as recited in the respective claims." The examiner does not state that the entire carrier is moveable or more specifically deflectable. However, Applicant is not strictly claiming that the "entire carrier is moveable" but instead claiming "a carrier movable between an unstressed state and a deflected and stressed state." Broadly interpreted, element (12) of Gadsby meets the functional limitation, as a portion of (12) is movable between an unstressed state and a deflected and stressed state.

Next on page 9, first paragraph Applicant asserts

Gadsby fails to disclose, teach or suggest a carrier that is movable and "a tissue stimulation element supported by the carrier," or "a tissue engagement device carried by the carrier, the tissue engagement device being configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state," as recited in claim 1.

The examiner strongly disagrees. Gadsby discloses a carrier (12) that is moveable between an unstressed state and a deflected and stressed state as shown by figures 3 and 4. The tissue stimulation elements (18) are carried/disposed on the carrier (12) and the tissue engagement device (adhesive layer 22) certainly secures itself to the tissue and the carrier (12) to the tissue in the deflected and stressed state as well as in the unstressed state.

Next in the 2nd paragraph on page 9, Applicant asserts that Gadsby does not disclose the electrodes 18 are capable of stimulation. First, the term stimulation is interpreted very broadly by the examiner and Gadsby discloses that the electrodes affect the electrical impedance of the skin, see col. 2, lines 45-52. Therefore, the electrodes stimulate the tissue electrically and it should also be noted that piercing cone shapes of element (18) mechanically/tactilely stimulate the tissue.

In the last paragraph on page 9, Applicant asserts that elements (18) do not form a tissue engagement device "configured to secure itself to tissue and secure the carrier to the tissue in the deflected and stressed state." The examiner agrees they don't, the adhesive layer (22) forms the tissue engagement device.

All arguments/remarks by Applicant on pages 10 and higher regarding independent claims 8, 13, 16 and 34 are moot as either the grounds of rejection is new or the claims are objected to or allowable.

Allowable Subject Matter

Claims 34-37, 40 and 41 are allowed.

Claims 32 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane
May 10, 2007

A.R.


HENRY M. JOHNSON, III
PRIMARY EXAMINER